

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION

MDL 2804

OPIATE LITIGATION

Case No. 17-md-2804

This document relates to:

Hon. Dan Aaron Polster

Track One Cases

PLAINTIFFS' SUMMARY JUDGMENT ROADMAP

July 31, 2019

INTRODUCTION

On June 28, defendants filed a total of 27 separate motions for summary judgment against the claims brought by Summit and Cuyahoga Counties in this MDL (along with 14 separate *Daubert* challenges to Plaintiffs' expert witnesses). The defendants' summary judgment motions cover a wide range of topics and were brought by different groupings of defendants. Many of the motions raise overlapping legal issues and arguments. In order to most clearly and efficiently respond to defendants' motions, and to avoid needless redundancy, plaintiffs have opted not to respond separately to each motion for summary judgment, but rather to organize our opposing memoranda in a manner that seems to make the most logical sense and thereby to ease the burden on the Court.

Plaintiffs are therefore today filing only 18 separate memoranda in opposition to Defendants' 27 summary judgment motions.¹ This memorandum, the 19th, is intended to provide a "roadmap" for the Court to help understand the organization of plaintiffs' responses, to identify the summary judgment motions to which each memorandum responds, like the roadmap briefing the parties provided to the Court on June 25th in advance of the filing of the motions, and to summarize for the Court the central issues raised by these motions and oppositions. While all of defendants' motions should be denied, we also respectfully suggest a sequence for the Court in considering them that is likewise intended to prioritize its review and conserve the Court's resources.

DISCUSSION

The defendants' summary judgment motions fall into three main groupings:

1) The defendants collectively filed nine motions, roughly corresponding with "Tranche One" in Special Master Cohen's June 21, 2019 Amended Order Regarding Pretrial Motions for "Track One"

¹ To be precise, in these 18 memoranda plaintiffs are responding to 26 of the 27 summary judgment motions filed by defendants. Because Plaintiffs intend to move to sever their claims against defendant Noramco, Inc. from the CT1 trial, Plaintiffs are not filing a response to Noramco's Motion for Judgment on the Pleadings or, In the Alternative, Summary Judgment (Dkt. # 1902), while reserving all rights to proceed against that defendant at a later time and in other MDL lawsuits.

Trial, Dkt. #1709, that address three significant issues that cut across plaintiffs' claims against all defendants and many of Plaintiffs' claims: causation; conspiracy or concert of action, (including claims brought under RICO and OCPA), and statutes of limitation;

2) Certain groups of defendants also filed seven additional motions that focused on five discrete legal issues that are relevant only to particular defendants, particular claims or, in some cases, particular allegations within claims: preemption, negligence per se, public nuisance, manufacturers of generic opioids, and distributors with allegedly *de minimis* market shares;

3) Finally, ten defendants² (or families of defendants) filed individual motions for summary judgment seeking dismissal of plaintiffs' claims against them.

Plaintiffs believe that these three categories roughly correspond with the significance of the motions to the overall litigation; Plaintiffs therefore recommend that the Court take up the motions in order of these groupings.

Plaintiffs outline below their responses to each of these three sets of summary judgment motions.

TRANCHE ONE: CAUSATION, CONSPIRACY/RICO/OCPA, STATUTE OF LIMITATIONS

Rather than respond separately to each of the nine summary judgment motions raising Tranche One issues, plaintiffs have opted to file a single, consolidated opposition on each of the three Tranche One issues.

CAUSATION

Manufacturer, Distributor, and Pharmacy Defendants filed three separate motions challenging Plaintiffs' evidence that their misconduct caused the harms experienced by Cuyahoga and Summit

² Excluding Noramco, *see supra* note 1.

Counties as a result of the opioid crisis.³ The arguments in all three motions overlap substantially. Defendants argue, *inter alia*, that plaintiffs should not be allowed to establish causation through aggregate proof; that Plaintiffs have no actual evidence that their misconduct caused excessive prescribing and/or diversion of shipments of opioid drugs; that Plaintiffs cannot establish that such excess prescribing or diversion caused them harm; and that many of Plaintiffs' injuries are too remote from Defendants' alleged misconduct to satisfy the requirements of proximate cause.

Plaintiffs respond to all three of these motions with a single opposition: Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation (PSJ2). Plaintiffs' causation opposition Statement of Facts demonstrates ample evidence raising genuine disputes of material fact, that: 1) all of the manufacturer defendants engaged in fraudulent marketing to expand the market for prescription opioids; and 2) none of the defendants complied with their legal obligations to maintain effective controls against diversion of prescription opioids. Plaintiffs' experts also provide evidence that defendants' misconduct caused harm and damages to Plaintiffs. The causation opposition Argument shows, that, *inter alia*, 1) there is a general dispute of material fact under the applicable substantial-factor test that defendants' conduct was both a cause-in-fact and a proximate cause of plaintiffs' injuries; 2) the harm plaintiffs have suffered was the direct and foreseeable result of defendants' misconduct; 3) Plaintiffs have multiple sources of evidence to establish causation, not limited to expert testimony; 4) plaintiffs can and do prove causation through valid and reliable statistical analyses of aggregate proof, as widely accepted by courts; and 5) Defendants' unsubstantiated arguments concerning alleged intervening causes do not provide a basis for summary judgment and must be rejected.

³ Mem. of Law in Support of Pharmacy Defs.' Mot. for Summ. J. on Causation (Dkt. #1869); Mem. in Support of Distributor Defs.' Mot. for Summ. J. on Proximate Causation Grounds (Dkt. #1897); Manufacturer Defs.' Brief in Support of Mot. for Summ. J. for Pls.' Failure to Offer Proof of Causation (Dkt. #1941).

Given the centrality of the causation issues to all of the claims in this litigation, Plaintiffs encourage the Court to address these summary judgment motions first, before turning to the narrower or more-defendant specific motions.

CONSPIRACY/RICO/OCPA

Defendants have collectively filed four separate motions for summary judgment on plaintiffs' claims alleging that some or all defendants acted in concert in their fraudulent marketing and/or their decisions not to report or stop suspicious orders in order to grow the market for opioids and maintain an uninterrupted supply: two motions addressed to plaintiffs' civil conspiracy claims, one motion directed at plaintiffs' RICO and OCPA claims, and a motion filed by the manufacturer defendants covering all of these claims.⁴ The motions largely argue that plaintiffs lack sufficient evidence of an agreement among the applicable group of defendants to establish the existence of a conspiracy or an association-in-fact enterprise under RICO.⁵

Plaintiffs are today filing a single memorandum in opposition to all four of these motions entitled Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO, and OCPA Claims (PSJ3). Plaintiffs' opposition demonstrates that Plaintiffs have ample evidence of coordination and agreement among the defendants to create genuine disputes of material fact about the existence of the RICO Marketing Enterprise, the Opioid Supply Chain Enterprise, and a civil conspiracy among defendants to expand the market for prescription opioids and to ensure the continued availability of those drugs, despite defendants' obligations under the Controlled Substances Act (CSA). The opposition also establishes

⁴ Mem. in Support of Distributor-Defendants' Mot. for Summ. J. on Civil Conspiracy Claim (Dkt. #1692); Mem. in Support of Pharmacy Defs.' Mot. for Summ. J. on Pls.' Civil Conspiracy Claim (Dkt. #1716); Mem. in Support of Distributor Defs.' Mot. for Summ. J. on Pls.' RICO & OCPA Claims (Dkt. #1904); Mem. in Support of Manufacturers' Joint Mot. for Summ. J. on Pls.' RICO, OCPA, & Conspiracy Claims (Dkt. #1930).

⁵ Defendants do not, in these motions, dispute plaintiffs' allegations that they have committed predicate acts sufficient to constitute a pattern of racketeering activity in furtherance of the alleged RICO enterprises.

that, as this Court has already found, plaintiffs have alleged injuries for which damages are available under both RICO and OCPA.

In plaintiffs' view, the briefing details far more than sufficient facts to establish the existence of genuine issues of disputed facts under prevailing law on each of these claims and requires denial of these motions for summary judgment.

STATUTE OF LIMITATIONS

Defendants filed two motions for summary judgment on the statute of limitations: a combined motion by the distributor and manufacturer defendants and a separate motion by the pharmacy defendants.⁶ Neither motion seeks complete dismissal of plaintiffs' claims. Instead, defendants argue that the bulk of their alleged misconduct occurred prior to the start of the applicable limitations periods, and that they should be entitled to partial summary judgment as to all claims based on conduct before those dates.⁷

Plaintiffs today file a single opposition to these motions; Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Partial Summary Judgment on Statute of Limitations Grounds (PSJ4). Plaintiffs' opposition demonstrates that, contrary to defendants' arguments, the date by which plaintiffs knew, or should have become aware, of their injuries resulting from defendants' misconduct is a contested question of fact, and also documents defendants' considerable and affirmative efforts to conceal their roles in causing the opioid crisis. Plaintiffs proceed to explain that: 1) certain of their claims—public nuisance, unjust enrichment, and OCPA—are not subject to the statute of limitations at all under the facts presented by defendants, due to the

⁶ Combined Br. of Distributors & Manufacturers in Support of Partial Summary Judgment on Statute of Limitations Grounds (Dkt. #1892); Pharmacy Defs.' Mem. of Law in Support of Their Mot. for Summ. J. Based on the Statute of Limitations.

⁷ Two pharmacy defendants, Walgreens and CVS Indiana, contend that they stopped distributing opioids prior to the start of the limitations window and thus all claims against them should be dismissed. Dkt. #1872 at 3-4.

particular accrual rules applicable to those claims; 2) there is a genuine dispute of material fact as to when the plaintiffs knew or should have known of their injuries under the discovery rule applicable to their other claims; 3) plaintiffs should be entitled to equitable tolling of the statute of limitations due to their previous lack of access to ARCOS data; and 4) defendants' fraudulent concealment of their noncompliance with their duties to prevent diversion tolls the running of the statute of limitations as to those claims. As plaintiffs' opposition further explains, regardless of this Court's ruling on these motions, evidence of defendants' pre-2012 misconduct will be both relevant and admissible at trial to establish defendants' liability for damages within the limitations period. Accordingly, there is less urgency to the Court's resolution of these motions, although an early ruling would provide important guidance to the parties as to how best to organize their presentation of evidence at trial.

CATEGORY 2: MOTIONS ADDRESSING DISCRETE LEGAL ISSUES

Seven motions filed by various groups of defendants raise five discrete legal issues: preemption, negligence per se, public nuisance, manufacturers of generic opioids, and distributors with allegedly *de minimis* market shares. Plaintiffs are filing an opposition memorandum for each of these five subjects.

PREEMPTION

Defendants filed three motions asserting that certain of plaintiffs' state-law claims, or aspects of those claims, are preempted by federal law.⁸ Defendants assert a hodgepodge of different theories of preemption. The small distributors contend that plaintiffs' claims based on "fraud on the DEA" are preempted based on the reasoning of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); the manufacturer defendants reiterate that *Buckman* argument and also argue that plaintiffs' fraudulent

⁸ The Non-RICO Small Distributors' Mem. in Support of Their Mot. for Partial Summ. J. on Pls.' "Failure to Report" & "Fraud on the DEA" Claims (Dkt. #1873); Mem. of Law in Support of Mot. for Summ. J. on Preemption by Pharmacy Defs., ABDC, Cardinal, & McKesson (Dkt. #1897); Mem. of Law in Support of Manufacturer Defs.' Mot. for Summ. J. that Pls.' State-Law Claims are Preempted & Their Federal Claims are Precluded (Dkt. # 1926).

marketing claims are preempted by clear evidence the FDA had rejected labeling changes that plaintiffs ostensibly assert are required;⁹ and the pharmacies and large distributors contend that plaintiffs' claims against them are preempted because they interfere with the careful balance of "purposes and objectives" struck by Congress in enacting the CSA.

Plaintiffs respond to all of these arguments in a single opposition entitled Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Preemption Summary Judgment Motions (PSJ5). Plaintiffs explain that their claims are not preempted under *Buckman*, because plaintiffs' claims do not exist solely by virtue of federal law, but rather seek to enforce traditional tort duties under state law that are consistent with and parallel duties imposed by the CSA; for similar reasons, those claims do not interfere with the purposes and objectives of the CSA. As for the manufacturers' clear evidence preemption argument, plaintiffs do not challenge the FDA-approved labeling of any of the manufacturers' products, but rather their false and misleading promotion of those drugs, which was not permitted, let alone required, by federal law. Nor have the manufacturers shown that plaintiffs' fraudulent marketing claims conflict in any way with formal regulatory actions taken by the FDA.

Many of defendants' preemption arguments reiterate arguments that were already rejected by this Court in rulings on defendants' motions to dismiss. Plaintiffs therefore urge the Court to deny these new motions as well.

NEGLIGENCE PER SE

Only the distributor defendants move for partial summary judgment of plaintiffs' negligence claims to the extent these are based on the doctrine of negligence *per se*, largely on the basis of this Court's ruling on the motions to dismiss in the tribal cases (Dkt. # 1680 at 25).¹⁰ In plaintiffs'

⁹ The manufacturer defendants also argue that plaintiffs' RICO claims are precluded to the same extent that plaintiffs' state-law claims are preempted.

¹⁰ Mem. in Support of Distributor Defs.' Mot. for Summ. J. on Pls.' Negligence Per Se Claims (Dkt. #1861). Although the distributors style this motion as one to dismiss "claims" for negligence *per se*, plaintiffs have included no such claim in

opposition,¹¹ we explain that local governmental entities with responsibility for enforcing drug laws for the protection of the community, such as Summit and Cuyahoga County, are intended beneficiaries of the CSA and thus may invoke violations of that act to establish negligence per se. In any event, as the response further explains, evidence of the defendants' CSA violations will be admissible in support of plaintiffs' negligence claims regardless of whether negligence per se is available.

PUBLIC NUISANCE

Only the manufacturer defendants move for summary judgment on plaintiffs' two public nuisance causes of action, largely reiterating arguments that this Court already rejected on the motion to dismiss.¹² In plaintiffs' opposition, we explain that summary judgment should be denied because plaintiffs 1) have appropriately defined a public nuisance under Ohio law; 2) have presented sufficient evidence on each element of the cause of action to create triable issues of fact on plaintiffs' equitable public nuisance claim; and 3) can show predicate violations by each manufacturer defendant of laws controlling the distribution of drugs of abuse, including *inter alia* the CSA, to support plaintiffs' statutory public nuisance claims.¹³

GENERIC MANUFACTURERS

Defendant-manufacturers of generic prescription opioids moved for partial summary judgment as to plaintiffs' fraudulent marketing claims, ostensibly on the grounds that they do not "promote the safety and efficacy of their medicines." They also make a brief argument that any "failure-to-warn" claim against a generic drug manufacturer is preempted.¹⁴ Plaintiffs' opposition to

their complaints, though plaintiffs do assert the doctrine as one of several bases for liability under their negligence causes of action.

¹¹ Pls.' Mem. in Opp'n to Distributor Defs.' Mot. for Summ. J. on Pls.' Negligence *Per Se* Claims (PSJ6).

¹² Manufacturer Defs.' Mem. in Support of Mot. for Summ. J. on Pls.' Public Nuisance Claims (Dkt. #1942).

¹³ Pls.' Mem. in Opp'n to Manufacturer Defs.' Mot. for Summ. J. on Pls.' Public Nuisance Claims (PSJ7).

¹⁴ Generic Manufacturers' Mem. in Support of Mot. for Partial Summ. J. (Dkt. #1860).

this motion provides substantial evidence to refute the assertion that these generic manufacturers did not “promote the safety and efficacy of their” opioid drugs, creating a genuine dispute of material fact sufficient to defeat summary judgment; plaintiffs also demonstrate that defendants’ preemption argument has no application to plaintiffs’ claims, as this Court has already held.¹⁵ The Court can readily deny this motion by finding the existence of a genuine dispute of material fact.

“*DE MINIMIS*” DISTRIBUTORS

Four distributor defendants who were not named in plaintiffs’ RICO counts move for summary judgment on the grounds that their market share was so small as to be *de minimis* and not a legal cause of plaintiffs’ injuries.¹⁶ Plaintiffs’ opposition documents that the market share for these distributors was larger than they assert and that, in any event, the millions of MMEs and dosage units they distributed into Summit and Cuyahoga Counties can hardly be deemed *de minimis*; plaintiffs also document these distributors’ startling noncompliance with their SOMs obligations and, for certain of these distributors, their outsized role in supplying opioids directly to “pill mill” doctors and pharmacies in the plaintiff jurisdictions.¹⁷ Because substantial evidence demonstrates genuine disputes of fact, summary judgment should be denied.

In several of the motions in this category, the moving defendants invoke and incorporate by reference arguments made in some of the Tranche One motions, especially arguments as to causation. Rather than repeating plaintiffs’ lengthy responses to these arguments, plaintiffs likewise incorporate by reference the relevant portions of their Tranche One oppositions.

¹⁵ Pls.’ Mem. in Opp’n to “Generic Manufacturers” Mot. for Partial Summ. J. (PSJ8).

¹⁶ Mem. in Support of Non-Rico Small Distributors’ Mot. for Summ. J. Based on Their *De Minimis* Status (Dkt. #1879).

¹⁷ Pls.’ Mem. in Opp’n to Non-RICO Small Distributors’ Mot. for Summ. J. Based on Their *De Minimis* Status (PSJ9).

CATEGORY 3: DEFENDANT-SPECIFIC MOTIONS

Finally, in the third category, there are ten motions brought by individual defendants: specifically, Allergan (Dkt. #1940), CVS (Dkt. #1886), Discount Drug Mart, Inc. (Dkt. #1862), HBC Service Company (Dkt. #1912), Janssen Pharmaceutical Inc. (Dkt. #1922), Mallinckrodt (Dkt. #1898), Rite Aid of Maryland (Dkt. #1870), Teva and Activis (Dkt. #1891), Walgreens (Dkt. #1871), and Walmart (Dkt. #1866). Plaintiffs are today filing separate oppositions to each of these motions, designated for filing purposes as PSJ10 through PSJ19, respectively.

Plaintiffs will not here discuss in any detail the defendant-specific motions or plaintiffs' oppositions thereto. The defendant-specific motions are largely, though not exclusively, "me-too" motions that repeat or cross-reference arguments found in defendants' more general motions on, *e.g.*, causation, conspiracy, statutes of limitation, and preemption, or reiterate legal arguments that were already rejected in the motions to dismiss. They also generally assert that plaintiffs lack sufficient evidence to proceed to trial against them.

In responding, plaintiffs have tried to the extent possible, not to repeat arguments made elsewhere. We frequently incorporate our responses to the more general motions by reference. As a result, the defendant-specific responses tend to focus heavily on the facts, and the evidence plaintiffs have gathered as to that particular defendant that demonstrates their legal liability to plaintiffs. Of course, where a defendant-specific motion raises a unique legal argument not already addressed elsewhere, plaintiffs respond to that argument in our defendant-specific response.¹⁸

Because the legal arguments raised in these motions are largely repeated from other motions, and because we provide considerable evidence concerning each defendant's culpability in our

¹⁸ The motion brought by Allergan is one good example. Allergan argues that it cannot be held liable for the marketing of Kadian before it acquired the drug from Alpharma in 2009, nor for the marketing activities of its former generic subsidiary Actavis, which it sold to Teva in 2016, due to the terms of the applicable corporate transfer agreements. Dkt. # 1940 at 4-5. Plaintiffs respond directly to these arguments, and demonstrate the basis for Allergan's liability for its own misconduct, in Plaintiffs' Memorandum in Opposition to Allergan Defendants' Motion for Summary Judgment (PSJ10).

responses, we believe that it should not be difficult for the Court to deny summary judgment on the grounds that genuine disputes as to material facts exist.

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Respectfully submitted,

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